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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,600	05/23/2001	Virginia Smith-Swintosky	PRI-0014 (ORT-1436)	9298

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/863,600	SMITH-SWINTOSKY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: See continuation

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *38-52*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

JON WEBER
SUPERVISORY PATENT EXAMINER

Continuation of 2. NOTE: It is noted that Applicant has added claims 53 and 54. The added claims are directed to a method for promoting neurite outgrowth in a patient by administering to said patient an effective amount of one or more monomeric peptides claimed in claims 53 and 54. Newly added claims 53 and 54 raise new issues with respect to the scope of the claims since the claims are now broadened generally without any limitations or conditions to a method for promoting neurite ourgrowth in a patient by administering to said patient an effective amount of one or more monomeric peptides claimed. While, previously presented claims are directed to a method for treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient a therapeutically effective amount of one or mnore monomeric peptides (See e.g., independent claim 38). Similarly independent claim 52 is directed to a method for promoting neurite ourgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient an effective amount of one or more monomeric peptides. Thus, newly added claims 53 and 54 broaden the scope of the claimed invention generally to a method for promoting neurite outgrowth in a patient by adminsitering the peptides claimed which were not dealt previously, and as such would require further consideration and search. Although, the amendment filed 8/11/04 was not entered for the reasons discussed above, Applicant argued that there is no evidence of record so much as suggesting that those skilled in the art would be unable to practice the cliamed invention because the present specification provides ample support and enablement for the claimed methods of promoting neurite outgrowth in a patient and treating conditions mediated by neurotoxicity, neurodegeneration or neurological damage is unpersuasive.

Contrary to Applicant's arguments as discussed in the previous Office action, the Examiner has shown that the specification provides evidence that the recited EPO mimetic peptides stimulate neurite outgrowth in cell culture and that EPO has neuroprotective activity; however, for the reasons discussed previously, the peptides cannot be expected to be useful at promoting neurite outgrowth in a patient or treating a patient having a condition that can benefit from neurite outgrowth such as conditions mediated by neurotoxicity, neurodegeneration, or neurological damage in the manner claimed in the instant invnetion.

In regard to Applicant's assertion that Applicant has provided data in the specification demonstrating the nexus between EPO and/or EPO mimetics and treatment of the recited conditions and cited for example, Cerami et al. Nephrol Dial Transplant 2002; 17 Suppl 1: 8-12 (enclosed as Exhibit A) and Genc et al., Brain Research, 2000 19-31 (enclosed as Exhibit B) to support the nexus between EPO and the treatment condition claimed is unpersuasive. Contrary to Applicant's assertion, the cited references by Applicant (i.e., Exhibits A and B) do not teach or disclose the claimed method of treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (particularly human) a therapeutically effective amount of a peptide comprising one or more monomeric peptides claimed. Further, as discussed in the previous Office action, the prior art clearly show the unpredictable nature and the complexity of the art in regard to treatment and/or promotion of neurite outgrowth of CNS disorders which include Alzheimer's disease, Parkinson's disease, Down's syndrome, Huntington's disease, etc. Therefore, considering the nature of the treatment and/or promotion of neurite outgrowth of CNS disorders and/or diseases by administering a therapeutically effective amount of the peptide claimed and the limited success achieved; one skilled in the art would not accept the instantly claimed invention as obviously valid and correct without demonstration of working example(s) or evidence or data for the following reasons:

In view of the fact that animals and humans are out bred, in view of the lack of disclosure of suitable animal models for a method of treating and promoting neurite outgrowth of CNS disorders or conditions or diseases, in view of the recognized problems in the art regarding effective treatment of diseases affecting the nervous systems (neuropathologies) and in view of the fact that it is difficult to regenerate the neurons in the living body; a reasonable doubt exists as to the enablement of the claimed method of treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (particularly human) a therapeutically effective amount of a peptide comprising one or more monomeric peptides claimed. Thus, the claims are based on pure speculation that the method would be effective since Applicant has not established any nexus between an effective amount of the claimed peptides and its use in the manner claimed.

Therefore, in view of the above, and in view of the fact that there is no enablement in the instant specification for methods of treating and promoting neurite outgrowth diseases of the nervous system by administration of composition having the neurological therapeutic activity of EPO; Applicant should present some data or evidence to establish the successful use of a method for treating and promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering the claimed peptide to a patient in order to fulfill 35 U.S.C. 112, first paragraph requirement. Secondly, the Examiner has clearly shown in the previous Office Action of Paper No. 23 (mailed 11/20/03) and Final Office action mailed 4/29/04 that without guidance through working example(s), one of ordinary skill in the art would not predict from background discussion and/or information and protocols to employ or administer the pharmaceutical formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without working example(s) or data or evidence. The law requires that a disclosure in an application shall inform those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al., 166 USPQ 138 (CCPA 1970). Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claims 38-52, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above. Thus, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims for the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Therefore, the previous rejection under 35 U.S.C. 112, first paragraph is maitained for the reasons of record.